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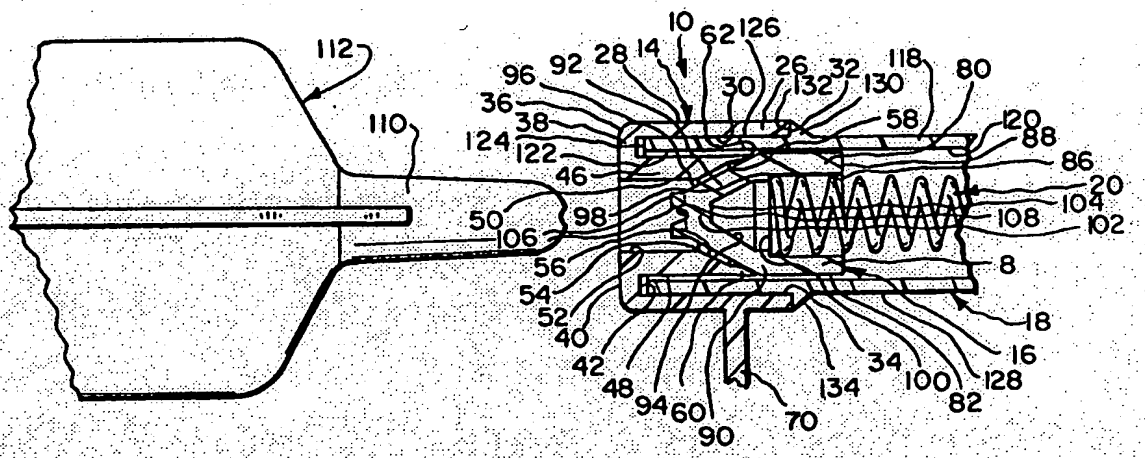

(57) Abstract

Apparatus and methods by which a closed ventilating system accommodates access to the respiratory tract of an intubated medical patient for selective introduction of therapeutic liquids, to flush with washing solution and/or to administer medication and/or to introduce lavage, without compromising the closed character of the system. The apparatus comprises a normally closed valve mechanism having a valve seat (40/60), a valve member (16), and a bias spring (20). The valve member is opened by a physical force imposed by a container (112) from which liquid is introduced. Two-way fluid flow across the valve member takes place.

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-- BIASSED LIQUID DELIVERY VALVE ARRANGEMENT--

Technical Field

The inventions disclosed herein relate generally to apparatus and methods for improved medical care for intubated patients, and more particularly to novel devices and related methods, for selective delivery of liquid to the respiratory tract of intubated medical patients, including infants, adolescents, and adults.

Background Art

Respiratory patient care is a dynamically developing field in medicine, ranging in its needs from infants to the aged. The range of respiratory ailments, both temporary and permanent, to which such patients are subjected are many and varied. The frontier of medical knowledge is advancing and recommended treatments have become a blend of old and more recent discoveries.

Most problems now center or focus on multiple needs of the patient and accommodation of multiple treatments, some to be performed at the same time. The lack of equipment to facilely, efficiently, and safely accomplish the multiple therapies in the best interest of the patient has been and continues to be a concern. Other equipment problems also exist which concern preventing cost-oriented, unsafe extended use of ventilating, aspirating, and other respiratory access apparatus, reliability during use, quick and reliable removal and exchange of spent aspirating and ventilating devices without compromising the quality of health care provided to the patient, avoiding intentional or inadvertent conversion from a closed system to an open system, prevention of stress and/or occlusion of flow passageways to and from

the patient's respiratory system, avoidance of a large inventory of a variety of incompatible products, providing easy, fail-safe access for multiple purposes.

By way of an example only, with low lung capacity patients, such as premature babies and adults suffering from emphysema, one problem is the removal of accumulated lung secretions without starving the patient for oxygen (thereby causing undesirable side effects) during the secretion removal process.

Sight must not be lost as to the deficiencies in prior proposals in terms of risks created for the health care provider. Largely, proposals of the past have ignored the needs of the health care provider to attain a reasonable measure of protection from contamination by the patient.

Providing apparatus and methodology having the capacity to promptly, efficiently, safely, and cost effectively address the health care needs of intubated patients across the entire spectrum of respiratory ailments has been an important though frequently unachieved goal. The range of procedures comprise: ventilating, aspiration, oxygenation, sampling, visual inspection, in-line sensing, pressure monitoring, flushing, and medication and/or lavage. Introduction of liquids into the respiratory system of a medical patient, to flush, medicate, irrigate, or the like, has often been awkward and without adequate control. It too often risks opening a closed system to outside contamination. Leakage under pressure and clogging are frequent faults. Delivering repeated doses of liquid from the same container in rapid succession has been difficult.

Disclosure of the Invention

In brief summary, the present invention substantially alleviates the aforesaid problems of the prior art and comprises apparatus and methods by which a closed ventilating system accommodates access to the respiratory system of an intubated medical patient for various purposes, including selective introduction of therapeutic liquids, without compromising the closed character of the system. Access to the respiratory system through one or more access sites of the closed system apparatus is provided to ventilate the lungs of the patient with gas or gases, to aspirate secretions from the lungs, to oxygenate the lungs to eliminate or reduce residual CO_2 therefrom, to visually inspect selected parts of the respiratory system, to sample sputum and gases, to sense parameters such as flow rates, pressure, and temperature, to flush with washing solution, and/or to administer medication, gases, and/or lavage. The technology of the present invention has substantial universal application to all respiratory patients, ranging from infants to the aged.

The system comprises apparatus and methods by which liquids are selectively introduced through a ventilating device into the respiratory system of a medical patient to flush, medicate, irrigate, or the like. Use is facile and requires little training. Control is easily achieved. Risks that the closed system will become materially open to external contaminates is low. Leakage under pressure and clogging are obviated. Repeated doses or discharge cycles of liquid are readily accommodated by a novel two-way valving technique.

It is a primary object of the present invention to provide apparatus and related methods by which a closed ventilating system is able to accommodate multiple access to the respiratory system of an intubated medical patient, including access for selective introduction of liquid into the respiratory system for one or more purposes.

An additional paramount object is the provision of novel apparatus and related methods by which a closed ventilating system accommodates multiple access including access for introduction of liquid into the respiratory

system of an intubated medical patient without substantially compromising the closed character of the system.

An additional object of the present invention is the provision of access through one or more access sites in a closed system respiratory apparatus in such a way as to medicate, irrigate, and/or flush the lungs of the patient, among other things.

It is another dominant object to provide a respiratory health care system and related methods which has substantial universal application to all respiratory patients ranging from infants to the aged.

A further important object of the present invention is to provide features in a respiratory health care system which accommodate selective introduction of liquid through a ventilating device into the respiratory system of a patient to flush, medicate, irrigate, or the like.

It is a prominent object of the present invention to provide respiratory health care systems and related methods which accommodate simultaneous gas and liquid treatment of the respiratory system of a medical patient.

It is a further object of the present invention to provide novel respiratory health care systems and related methods comprising a liquid introduction system which is facile and requires little training.

It is another paramount object to provide valve mechanisms which accommodate selective liquid introduction into the respiratory system of a medical patient.

Another valuable object is the provision of a novel flow control for introduction of liquid through a closed ventilating system into the respiratory system of a medical patient which has one or more of the following advantages: easily controlled, substantially retains the closed nature of the system, is essentially leak proof, does not clog, and accommodates a plurality of pressure discharges of liquid in rapid succession by a novel two-way flow technique.

It is a further object of major significance to provide for selective introduction of liquid into the respiratory tract of a medical patient in such a way as to reasonably protect the health care provider.

These and other objects of the features of the present invention will be apparent from the detailed description taken with reference to the accompanying drawings.

Description of the Drawings

Figure 1 is a perspective representation of a mechanism for introduction of liquid into the respiratory system of a medical patient, embodying principles of the present invention;

Figure 2 is an exploded perspective of the mechanism of Figure 1;

Figure 3 is a longitudinal cross-section of the various components of the mechanism of Figure 3 shown in exploded relationship;

Figure 4 is a cross-sectional representation primarily of the piston valve and valve seat in closed relationship with a container of liquid about to be inserted into the valve seat displace the piston valve;

Figure 5 is a cross-sectional representation similar to Figure 4 showing the male end of the liquid container inserted into the valve seat causing the piston valve to be displaced into an open position, with the liquid container forcibly dispensing liquid;

Figure 6 is a cross-sectional representation similar to Figure 5 showing the piston valve in its open relation, caused by the male discharge end of the liquid container with air flowing around the valve into the container to reinflate the container after liquid discharge;

Figure 7 is a cross-section taken along lines 7-7 of Figure 3;

Figure 8 is a cross-section of a second valve member embodying principles of the present invention;

Figure 9 is an elevation, with a portion shown in section for clarity, of still another valve member integrally joined to a flat accordion-type spring;

Figure 10 is an elevation, with a portion shown in section for clarity, of a further valve member integrally joined to a flat accordion-type spring;

Figure 11 is an elevational view taken along lines 11-11 of Figure 10; and

Figure 12 is a fragmentary elevation with a portion broken away for clarity of a modification of the valving member of Figures 10 and 11.

Modes for Carrying out the Invention

Reference is now made to the drawings, wherein like numerals are used throughout to designate like parts. The illustrated embodiment is intended to be representative of inventive principles by which liquid may be selectively and appropriately introduced into the respiratory system of a medical patient through any one of several flow-accommodating devices. The purpose of the liquid is not limited to but may include irrigation, flushing, and medication. The particular location of the illustrated mechanism for selective introduction of liquid into the respiratory system of a medical patient is not restricted and includes displacement through tubes, catheters, various flow devices, and the like. In one desirable form, the present mechanism may be used at one access port while other therapeutic devices access are being used at other sites. It follows that the described embodiments are only illustrative or representative of principles of the present invention.

Specifically, the Figures illustrate a closed system-preserving mechanism, generally designated 10, by which liquid may be selectively introduced through a respiratory treatment device, generally designated 12, into the respiratory system of a medical patient. The liquid introduction mechanism or apparatus 10 comprises a valve seat housing, generally designated 14, a two-way piston valve member, generally designated 16, a hollow barrel, generally designated 18, in which the piston valve member 16 selectively reciprocates and in which a coiled compression spring, generally designated 20, is disposed, a length of hollow tubing, generally designated 22, and a hollow elbow fitting, generally designated 24. While the liquid introducing mechanism 10 is illustrated as comprising a specific number of components, it is to be appreciated that components can be combined and separated, as will be readily apparent to those with skill in the art.

The valve seat housing 14 is preferably formed from a suitable material such as a medical grade synthetic resinous material or an elastomer such as synthetic rubber. Valve seat housing 14 comprises an exterior

cylindrical wall 26, illustrated as having a uniform thickness and a uniform outside diameter, at surface 28, and inside diameter, at surface 30. The distal end of the wall 26 terminates in a transversely-directed blunt edge 32 defining a distal opening 34 (Figure 3), the diameter of which is equal to the diameter of surface 30, of which opening 34 forms a part. Opening 34 accommodates receipt of both the proximal end of barrel 18 and piston valve member 16, as described hereinafter in greater detail.

The proximal end 36 of wall 26 merges through 90° with an inwardly-directed transverse or radial-directed flange 38, which comprises the blunt proximal end of the housing 14. Flange 38 is annular and comprises exterior surface 40 and interior surface 42. The annular flange 38 merges at corner 44 with a longitudinally-directed annular wall 46.

When not displaced, interior wall 46 is generally concentrically disposed within wall 26 and comprises an exterior cylindrical surface 48. Wall 46 also comprises an interior cylindrical surface 50, defining a proximal access port 52 and extending from proximal corner 44 to corner 54. Thus, the length of wall surface 50 is substantially shorter than the length of wall surface 48. The length of wall surface 48 is substantially less than the length of wall surface 28.

Cylindrical interior wall surface 50 merges with a forwardly divergent diagonal wall surface 56, which is illustrated as being that of a truncated cone, extending between corner 54 and corner 58. In effect, diagonal surface 56 comprises a step or reduction in the thickness of wall 46 to a thinner although tapered distal lip 60. Lip 60 is relatively thin being tapered distally to a distal point 62.

While all parts of wall 46 are formed as one-piece, as is all of housing 14, the lip 60 is yieldable or pliant and conforming and defines at its tapered interior surface 64 a valve seat, for a purpose hereinafter explained in greater detail. As can be seen from observation of Figure 3, wall 46 has a longitudinal or axially dimension substantially less than the longitudinal or

axial dimension of annular wall 26 to accommodate placement and seating of the piston valve member 16 during use.

Formed as one piece with wall 26 is an integral tether 70. Tether 70 is illustrated as being rectangular and solid in cross-section, although other configurations could be used. Tether 70 merges in one piece relationship with both wall 26 and a cap, generally designated 72. Cap 72 comprises a cylindrical wall 74 of uniform thickness comprised of uniform inside and outside diameters. The inside diameter is slightly less than the outside diameter of housing 14, at surface 28. The axially dimension of wall 74 is substantially less than the axially or longitudinal dimension of wall 26.

The cylindrical wall 74 merges with a radially-directed planar end wall 76, which may be of uniform thickness. Wall 76 is formed as one piece with wall 74 to collectively define a cup-shaped hollow interior. Wall 76 at its interior surface is interrupted by a cylindrical stud 78 which comprises a blunt end wall 81 as well as a cylindrical wall surface 87. The diameter of wall 87 is preferably selected so as to be slightly less than the diameter of opening 52 of held in position by a manually-releasible compression fit between the knob 78 at surface 82 and housing 14 so that when cap 76 is placed over the proximal end of housing 14, cylinder 78 fits loosely within opening 52 and spaced from surface 50.

To remove cap 72 from its press-fit relationship over the proximal end of the valve seat housing 14, a tab 89 is provided. Tab 89 is illustrated as being formed as one piece with wall 74, as having a cross-section substantially the same as the cross-section of tether 70 (although other configurations could be used), and extending a distance sufficiently away from cap 72 to allow manual grasping of the tab 89 for removal of the cap 72 from placement over the proximal end of the housing 14.

The piston valve member 16 is preferably formed as one piece from suitable synthetic resinous material, such as nylon or celcon, which is shape-retaining and rigid in its configuration. Piston valve member 16

accommodates two-way fluid flow, as explained hereinafter in greater detail, and comprises a bullet-shaped configuration with a hollow interior. More specifically, piston valve member 16 comprises a wall 80, which comprises an outside surface 82 and a cylindrical inside surface 84.

As can be best seen from reference to Figure 7, outside surface 82 comprises in series four flat top, bottom, and side surfaces 83. The inside surface 84 defines part of a hollow blind bore interior which comprises an opening 86. Wall 80 comprises a blunt, transversely or radially-directed distal edge 88 and merges at a diagonal corner 90 with a truncated cone-shaped wall 92. Cone-shaped wall 92 comprises smooth tapered interior and exterior surfaces 94 and 96, respectively. Inside surfaces 94 and 96 are interrupted by an inwardly projecting annular shoulder or ledge 98 against which the proximal end 100 of coiled spring 20 forcibly rests in the assembled position. See Figures 4-6.

Cone-shaped wall 92 merges with a proximal closure wall 102. Wall 102 comprises an interior flat radially-directed flat surface 104 and an exterior contoured surface 106. As best seen in Figure 2, exposed contoured surface 106 is somewhat diamond-shaped and comprises two grooves 108, which cross each other at 90°. Other groove or recess configurations could be used.

The contoured surface 106 at the proximal end or tip of the piston valve member 16 accommodates contiguous engagement by a male discharge end 110 of a liquid storage container, generally designated 112 (Figures 4-6), displacement of liquid under pressure from container 112 through the hollow of male projection 110, along grooves 108, the exterior conical surface 96, and thence primarily across flats 83 to the hollow interior of the barrel 18. Similarly, opposite flow of ventilating gas present in the hollow of barrel 18 is accommodated, primarily from the hollow of barrel 18 along the flats 83 of piston valve member 16, across cylindrical surface 96, along grooves 108 into the hollow of the male projection 110 and thence into the hollow of the

container 112 to reinflate or recharge the container thereby accommodating a second discharge of liquid therefrom, in the manner described. Manual projection 110, at the side thereof, snugly engages and seals at surface 50 to prevent fluid leakage and to protect the health care provider. It is to be appreciated that container 112 is intended to be representative of any device from which is manually pressurized and from which liquid is selectively discharged.

Spring 20 is sized and shaped so that proximal end 100 contiguously engages shelf, ledge, or shoulder 98, in the assembled condition. This urges the piston valve member 16 toward its closed position of Figure 4, so that valve seat 60 is deflected by and seals against surface 96 absent force imposed by the male projection 110. The distal end 114 of the coiled spring 20 forcibly rests upon internal surface 116 of barrel 18, in the assembled condition. See Figure 3.

The piston valve member 16 is supported in cantilevered relation upon the proximal portion of the spring 20, but is otherwise unattached to the assembly 10. Thus, piston valve member 16 is reciprocable to and fro within the hollow interior of the barrel 18, in response to the balance of forces being exerted by compressed spring 20, on one end, and the male end 110 of the liquid container 112, if any, on the other end. It is, therefore, to be appreciated that spring 20 has an unstressed length, as illustrated in Figure 3, greater than the distance between shelf or shoulder 98 and surface 116, when apparatus 10 is fully assembled. Therefore, in the assembled condition, spring 20 is partially compressed and, therefore, urges the piston valve member 16 into sealed relation at conical surface 96 with deflectable lip/valve seat 60, as illustrated in Figure 4.

Barrel 18 comprises a generally annular wall 118 comprised of a cylindrical interior surface 120 of uniform diameter throughout thereby creating a proximal opening 122 adjacent blunt transverse end 124 comprising part of a hollow interior.

Wall 118 comprises first and second cylindrical exterior surfaces 126 and 128. The length of surface 126 is illustrated as being slightly less than the length of surface 128. Surfaces 126 and 128 are interrupted or separated by an annular barb, shoulder, ledge, or shelf 130, which extends annularly and comprises a radially-directed surface 132 juxtaposed surface 126, and a diagonal surface 134, juxtaposed surface 128. The diameter of surface 126 is illustrated as being substantially the same as the diameter of surface 128. During assembly, barrel 18 is inserted through opening 34 into the hollow interior of the valve seat housing 14, between walls 26 and 46, but contiguous with surface 30. By application of adhesive, bonding agent, or through plastic welding, surfaces 126 and 132 are respectively bonded to surface board 332 to create a permanent assembly of the two components, as illustrated in Figures 4-6.

As can be seen from inspection of Figures 4-6, the diameter of interior cylindrical surface 120 is less than the maximum transverse dimension of wall 80 at exterior surface 83 and 85, so that normal concentric reciprocation of piston valve member 16 within the hollow interior of the barrel 18 is accommodated in spaced relation.

The distal end of the barrel 18 is convergingly tapered in a distal direction at non-linear surface 140, which is annularly concave in its configuration and extends between outside corner 142 and distal blunt edge 144. Concave surface 140 comprises part of wall 146. Wall 146 is formed as one piece with the rest of barrel 18 including a plurality of radially-directed internal spring-locating ribs 148, disposed within the hollow interior of wall 118. Ribs 148 merge with an inwardly-directed radially disposed annular apertured wall 150. While six ribs 148 are illustrated, any appropriate number may be used. The aperture 152 disposed in wall 150 is concentrically located and has a diameter substantially equal to the inside diameter of tube 22. Wall 150 also comprises previously mentioned proximal wall surface 116 upon which end 114 of spring 20 forcibly abuts in the assembled condition.

Radially disposed wall 150 merges as one piece with wall 146, the interior surface 154 of which is cylindrical and comprises a diameter substantially the same as the outside diameter of tube 22.

The proximal end 156 of tube 22 is fully inserted into the recess defined by surface 154 and wall 150 until the proximal edge 158 of the tube 22 is contiguous or nearly so with the distal surface of wall 120. With a suitable bonding agent or adhesive or using plastic welding techniques, the proximal end 156 of the tube 22 is permanently adhered into the described assembled position against inadvertent removal. Tube 22 also comprises a distal end 162 termination in a blunt transversely-directed edge 164 of annular configuration.

The barrel 18 is formed of a shape-retaining synthetic resinous material or elastomer which is compatible with material from which valve seat housing 14 is formed, each being of medical grade.

Similarly, tube 22 is formed of a suitable medical grade synthetic resinous material which is deflectable but tends to retain its shape so that the hollow interior 160 thereof is not inadvertently occluded. Thus, when flow of liquid or gas is accommodated by displacement of piston valve member 16 from valve seat lip 60, as described above, tube 22 accommodates and does not complicate such flow.

Elbow fitting 24 is formed of shape-retaining medical grade synthetic resinous or elastomeric material and comprises an integral body defined by a hollow proximal leg 166 and a hollow distal leg 168, the legs being illustrated as being disposed at 90° one in respect to the other. Other fitting configurations could be used in accordance with the ability of those having ordinary skill. Proximal leg 166 comprises a blunt end 170 and a tapered exterior surface 172. Proximal leg 166 comprises a hollow cylindrical passageway 174 defined by surface 176 illustrated as having a uniform diameter throughout. Passageway 174 terminates at distal edge 178. Distal end 162 is sized so as to be contiguous with surface 176 when inserted into

the passageway 174. Typically, edge 164 is caused to engage shoulder 177 during insertion. Using plastic welding, a bonding agent or adhesive, the distal end 162 is permanently retained in the inserted position against inadvertent removal.

Proximal leg 166 merges at corner 180 with distal leg 168. Distal leg 168 comprises a blunt distal edge 182 and is illustrated as further comprising an exterior cylindrical surface 184. Leg 168 is essentially an annular wall defining a cylindrical distal passageway 186 defined by interior cylindrical surface 188. Passageways 174 and 186 merge at edge 178 so that gaseous flow from suitable respiratory treatment device 12 to expand and recharge container 112 is accommodated, when valve member 16 is displaced from valve seat 64, as is manually pressurized liquid flow from the container 112 also when the piston valve member 16 is in its open condition. Contrast Figures 6 and 5, respectively.

Distal end 162 is sized so as to contiguously be inserted into the passageway 174 until edge 164 engages shoulder 177. Using plastic welding, bonding material or adhesive, the distal end 162 is retained in the inserted position against inadvertent removal.

One advantage of the present invention is the capability of simultaneously ventilating and administering liquid to the respiratory tract of a medical patient, consistent with the contents of co-pending U.S. Patent Application Serial No. 08/245,333 filed May 18, 1994, which is incorporated herein by reference.

Reference is now made to Figure 8 which illustrates a further valve member embodiment implementing principles of the present invention. The valve member of Figure 8 is generally designated 200 and is intended to be used in lieu of valve member 16 in conjunction with previously described spring 20 and previously described valve seat lip 60, in the manner heretofore described. Valve member 200 is generally spherically shaped and comprises a spherical wall 202, which is interrupted by a distally-directed stepped blind

bore 204. Wall 202 comprises a spherical exterior surface 206 and a spherical interior surface 208.

Outside surface 206 comprises at least one and preferably more than one fluid flow- accommodating groove 210, which serves the same purpose as that heretofore described in respect to grooves 108. Preferably the exterior proximal apex of surface 206 comprises at least two intersecting grooves 210. Spherical wall 202 is preferably formed of a synthetic resinous material which is shape-retaining and rigid, such as nylon or celcon. Wall 208 defines and forms a concave spherical blind bore 212. Wall 208 is stepped at shoulder 214 into diametrally enlarged cylindrical wall segment 216. The diametral size of spring end 100 is such that it is compression-fit against blind bore wall segment 216 so that the valve member 200 and the spring 20 are releasibly secured together against inadvertent separation. So positioned, end 100 rests in load-transferring relationship against shoulder 214 whereby valve element 200 is urged at all times toward a closed position in respect to the associated valve seat.

In the illustrated embodiment of Figure 8, the blind bore 204 is further enlarged or stepped at shoulder 218. Shoulder 218 merges with cylindrical wall segment 220 of the blind bore 204. The diameter of cylindrical wall segment 220 is larger than the maximum transverse dimension of spring 20 for ease of insertion of the spring 20.

Reference is now made to Figure 9 which illustrates a further embodiment of the present invention comprised of an integral valving or self-biasing spring member, generally designated 230. The biasing portion, generally designated 232, is comprised of a one-piece length of zig-zag synthetic resinous material where individual adjacent legs 234 thereof are interconnected respectively at living hinges 236. The plastic accordion-type spring 236 is disposed essentially in a plane and is, therefore, not coiled. The illustrated plastic spring 232 comprises an appropriately sized base 238 for engagement with surface 116 of barrel 18 in the assembled condition, to

compress, as explained above, the spring 232 and to thereby urge the associated valving element 240 into the closed position against valve seat lip 60.

The proximal end 242 of the spring 232 is embedded within the distal region of the valving element 240, when the valving element 240 is initially molded so that valving element 240 and spring 232 are essentially permanently united against inadvertent separation. The resulting member is self-biasing. Proximal end 242 connects to the remainder of the spring by short leg 239 and comprises an integral transversely-disposed washer 244, formed as one piece with spring 232. Washer 244 prevents fore and aft displacement of spring end 242 in respect to the valving element 240. Valving element 240, as illustrated, comprises a solid body of suitable synthetic resinous material which is shape-retaining and generally rigid. Nylon and celcon are suitable. Valving element 240 comprises a solid base 246, which comprises a cylindrical side surface 248 and a transversely-directed distal face 250 which is flat. Base 246 merges at corner 252 with a solid frusto conically-shaped proximal segment 254. Conical segment 254 comprises a truncated conically-shaped exterior surface 256, which, when the valve member 240 is normally closed, contiguously and sealingly engages valve seat lip 60 in seated relation, as explained above. Frusto-conically-shaped segment 254 merges at corner 258 with proximal tip 260, which is solid. Tip 260 comprises a side surface 262 which is generally cylindrical. Proximal tip 260 also comprises a contoured front surface 264 in which at least one and preferably two or more angularly disposed grooves 266 are disposed. The groove or grooves 266 function in the manner heretofore described in respect to grooves 108.

Reference is now made to Figures 10 and 11, which illustrate a further integrated composite self-biasing valving member, generally designated 270. Self-biasing member 270 comprises the previously described planar spring element 232 and a valving portion, generally designated 272. The

proximal end 242, with integral washer 244, is embedded in the valve member 272 at the distal end thereof in a manner substantially the same as described above in conjunction with valving member 240, the union occurring at the time valving element 272 is molded. Valving element 272 comprises a proximal solid piece of synthetic resinous material which is shape-retaining and rigid, such as nylon or celcon. Valving element 272 comprises a proximal hemisphere 274 which comprises an external spherical surface 276. Surface 276 is interrupted by at least one and preferably more than one groove 278 disposed at the proximal apex of the hemisphere 274. Where more than one groove 278 is used, it is preferred that the grooves be angularly intersecting. The one or more grooves 278 function for the purpose and in the same manner as heretofore described in connection with grooves 108. Hemisphere 274 comprises two spaced transversely-directed flat surfaces 280 and 282.

Surfaces 280 and 282 are interrupted by a distally-directed flange 284 which extends, as illustrated, in a vertical plane. Flange 280 is formed as one piece with hemisphere 274 at the time of molding. Flange 284 comprises a distal edge 280, which is generally circular or cylindrical. Flange 284 is centrally enlarged at boss 288, with spring end 242 extending into and being anchored within boss 288.

Self-biasing valving member 270 is placed within a valve the type heretofore described so that spring 234 continuously urges valving element 272 into a closed position against valve seat lip 60, when no other force is exerted on valving element 272. Yet spring 232 accommodates displacement of valving member 272 by the male discharge portion 112 of liquid container 110 in the manner and for purposes heretofore described.

Figure 12 illustrates a one piece valving/self-biasing member, generally designated 270′. Valving/self-biasing member 270′ is in all respects the same as member 270, except as explained below. Valving/self-biasing member 270′ comprises a valving element 272′, which is

substantially identical in structure and function to valving element 272, and biasing element 232', which is substantially identical in structure and function to biasing element 232.

Valving/self-biasing member 270' differs from member 270 in that elements 272' and 232' are formed as one piece rather than separately from a suitable synthetic resinous material, through well known injection molding techniques.

The invention may be embodied in other specific forms without departing from the spirit of essential characteristics thereof. The present embodiments therefore are to be considered in all respects as illustrative and are not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Claims:

1. A control mechanism for accommodating selective liquid access from an external source to a respiratory tract of an intubated medical patient comprising:

a hollow flow path-defining housing comprising a proximal end accommodating selective introduction of liquid into the mechanism and a distal end accommodating selective effluent liquid flow from and influent gas flow into the mechanism;

a valve mechanism comprising a valve seat carried by the housing, an impervious valve member carried within but reciprocable in respect to the housing and a biasing element associated with and urging the valve member into a normally closed, seated relation with the valve seat;

the housing comprising a proximal opening through which the valve member is displaced counter to the bias by an object comprising the external source of liquid accommodating liquid flow from the object between the seat and the valve member and between the valve member and the housing in the respiratory tract.

2. A control mechanism according to Claim 1 wherein the valve seat comprising an annular yieldable lip, which is distorted and diametrally enlarged when engaged by the valve member in the normally closed position.

3. A control mechanism according to Claim 1 wherein the valve seat is suspended from and concentrically disposed within the housing in spaced relation thereto.

4. A control mechanism according to Claim 1 wherein the valve member is bullet-shaped and comprises a conical surface which contiguously engages the valve seat when the valve mechanism is in its normally closed position and around which fluid flows when open.

5. A control mechanism according to Claim 1 wherein the valve seat comprises an annular yieldable lip and the valve member comprises a bullet-shaped configuration including a conical surface which contiguously engages, distorts, and diametrally enlarges the valve seat when the valve mechanism is in its normally closed position and around which fluid flows when open.

6. A control mechanism according to Claim 1 further comprising a removable proximal cap selectively usable to close the proximal opening during times of non-use.

7. A control mechanism according to Claim 6 wherein the cap is tethered to the housing.

8. A control mechanism according to Claim 7 further comprising a cantilevered tab connected to the cap for manually removing the cap from the housing.

9. A control mechanism according to Claim 6 wherein the cap comprises a male projection insertable into the proximal opening.

10. A control mechanism according to Claim 1 wherein the valve member is distally hollow and is cantileveredly supported by the biasing element.

11. A control mechanism according to Claim 10 wherein the biasing element comprises a coiled spring one end of which is located within the distal hollow of the valve member.

12. A control mechanism according to Claim 1 wherein the biasing element comprises a coiled spring.

13. A control mechanism according to Claim 1 wherein the valve member comprises a contoured fluid flow-accommodating proximal tip engaged by the liquid-containing object to open the valve mechanism.

14. A control mechanism according to Claim 13 wherein the contoured proximal tip comprises at least one groove by which a discharge opening in the object is maintained in fluid flow relationship in respect to the valve member when the valve is open so that liquid discharged from the object flows along the groove and across the external surface of the valve member between the valve member and the object, the valve seat and the housing, when the valve mechanism is open.

15. A control mechanism according to Claim 1 wherein the housing comprises
an assembly of hollow components, the components comprising seriatim a proximal valve seat housing, a barrel, a tube, and a distal fitting.

16. A control mechanism according to Claim 1 wherein the exterior of the valve member adjacent to the housing is contoured to insure the existence of at least one fluid path between the valve member and the adjacent housing.

17. A control mechanism according to Claim 1 wherein the proximal opening in the housing is sized and shaped to snugly engage a discharge portion of the object to prevent flow of liquid discharged from object through the proximal opening.

18. A control mechanism according to Claim 1 wherein the valve member is dome-shaped and comprises a surface which contiguously engages the valve seat when the valve mechanism is in its normally closed position and around which fluid flows when open.

19. A control mechanism according to Claim 1 wherein the biasing element comprises a one-piece element of synthetic resinous material disposed in a plane and comprising zig-zag legs interconnected by living hinges.

20. A control mechanism according to Claim 1 wherein the valve member and the proximal end of the biasing element are permanently joined.

21. A method of introducing liquid into the respiratory tract of a patient comprising the steps of:

engaging a normally closed impervious valve member with a male discharge portion of a device comprising a reservoir of liquid and forcibly displacing the valve member away from a valve seat counter to a bias force into an open position;

discharging liquid from the device through the male discharge portion and thence along a proximal tip and along the exterior of the valve member between the valve member, on the one hand, and the valve seat and a hollow flow accommodating housing on the other hand, to the respiratory tract;

withdrawing the device so that the male discharge portion no longer engages the valve member whereupon the bias force causes the valve member to resume its normally closed position.

22. A method according to Claim 21 wherein the discharging step comprises manually squeezing the device to pressurize the device and to discharge liquid therefrom.

23. A method according to Claim 21 wherein the discharging step comprises manually squeezing the device to pressurize the device and to discharge a less than adequate amount of liquid therefrom, removing the squeezing force allowing the device to be recharged with gas from the housing, the gas flowing between the housing and the valve seat on the one hand and the exterior of the valve member on the other hand and hence along the tip of the valve member and through the male discharge portion, following which the discharging and removing steps are repeated until ample liquid has reached the respiratory tract.

24. A two-way normally closed valve for selective introduction of liquid into the respiratory tract of a medical patient in one direction and recharging a liquid dispensing container with gas in the other direction comprising:

a hollow member;

a valve seat carried within the hollow member, the valve seat comprising an annular yieldable lip;

a valve member reciprocably disposed within and spaced from the hollow member and normally contiguously and sealingly closed against the lip, the valve member comprising a shape-retaining impervious body accommodating selective fluid flow only along the exterior thereof, the exterior comprising a proximally disposed lip-engaging sealing surface and a proximal end disposed within the housing and accessible from outside the housing;

a biasing element engaging and urging the valve member into closed, seated, and sealed relation with the lip;

whereby manually caused displacement of the valve member away from the lip into an open position sequentially accommodates said oppositely directed fluid flow.

25. A method of selectively introducing liquid into the respiratory tract of a medical patient in one direction and recharging a liquid dispensing container with gas in the other direction, comprising the steps of:

(a) biasing an impervious reciprocable valve member of a valve against a yieldable valve seat within a hollow flow-accommodating member to close the valve against flow in either direction;

(b) engaging a proximal site of the valve member with the container and displacing the valve member by force applied through the container distally to open the valve by separating the valve member from the valve seat;

(c) manually discharging liquid under manually-derived pressure from the container against the proximal site and thence along the exterior of the valve member to a location within the hollow member distal of the valve member, while the valve is retained in its open condition;

(d) relieving the pressure from the container while holding the valve member open followed by displacing of gas from the hollow member in a distal-to-proximal direction along the exterior of the valve member, across the proximal site, and into the container to recharge the container with gas capable of thereafter being pressurized manually;

(e) repeating step (c).

26. A method of delivering an ample quantity of therapeutic liquid sequentially to the respiratory tract of a patient comprising the steps of:

(a) displacing a biased normally closed impervious valve member from a closed to an open position;

(b) delivering a quantity of liquid under manually created pressure from a container around the valve member into the respiratory tract while holding the valve member in said open position;

(c) retaining the valve member in the open position, removing the manually created pressure, and recharging the container with gas flowing in a distal-to-proximal direction around the valve member and into the container;

(d) repeating step (b).

27. A method of subjecting a respiratory tract of an intubated medical patient to several simultaneously administered therapies comprising contemporaneously performing the steps of:

ventilating the respiratory tract;

introducing liquid into the respiratory tract by opening a normally closed access valve by physically displacing a valve member from a seated to an unseated position counter to a bias and displacing liquid under pressure across the exterior of the unseated valve member.

28. A method of directing liquid from a dispenser into the respiratory tract of an intubated medical patient comprising the steps of:

removably connecting the dispenser at a discharge end thereof to an exposed proximal end of a hollow member;

displacing a valve member located in the hollow member from a closed to an open position counter to a bias force by physical force imposed on the valve member by the liquid dispenser;

dispensing liquid from the dispenser against a proximal tip of the valve member, which alters the flow path of the liquid, thence around the valve member which further alters the flow path of the liquid and thence along the hollow member beyond the valve member.

29. A control mechanism for accommodating selective liquid access from an external source to a respiratory tract of an intubated medical patient comprising:

a hollow flow path-defining housing comprising a proximal end accommodating selective introduction of liquid into the mechanism and a distal end accommodating selective effluent liquid flow from and influent gas flow into the mechanism;

a valve mechanism comprising a valve seat carried by the housing, and an impervious self-biasing valving member carried within but reciprocable in respect to the housing comprising a proximal valving head and an integral distal biasing element urging the valving head into a normally closed, seated relation with the valve seat;

the housing comprising a proximal opening through which the valving head is displaced counter to the self bias of the biasing element by an object comprising the external source of liquid accommodating liquid flow from the object between the seat and the valve member and between the valve member and the housing in the respiratory tract.

30. A control mechanism according to claim 29 wherein the valving head is comprised of synthetic resinous material and a proximal end of the biasing element is embedded in the material comprising the valving head at a distal portion thereof.

31. A control mechanism according to claim 29 wherein the biasing element comprises synthetic resinous material.

32. A control mechanism according to claim 29 wherein the biasing element comprises a zig-zag configuration.

33. A control mechanism according to claim 32 wherein the zig-zag biasing element is substantially disposed in a common plane with a living hinge located between successive zig-zag legs.

34. A control mechanism according to Claim 29 wherein the valving element and the biasing element are of one-piece construction.

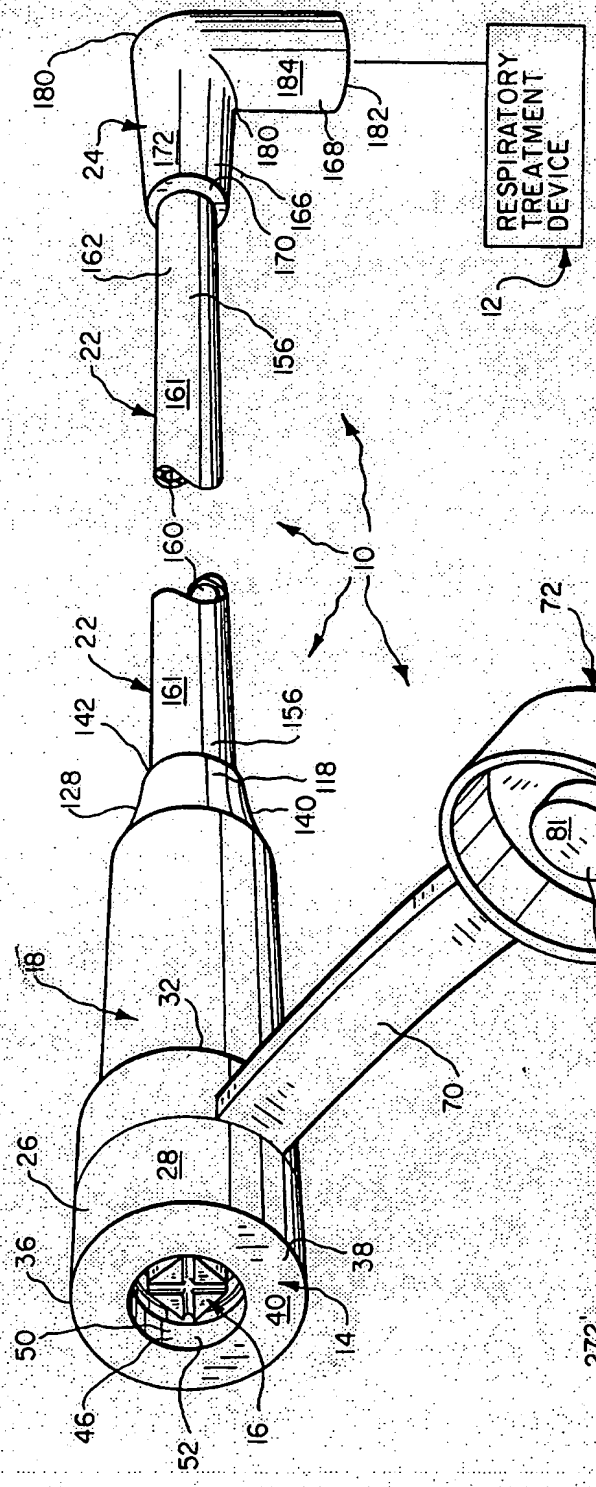
RESPIRATORY TREATMENT DEVICE
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FIG. 1

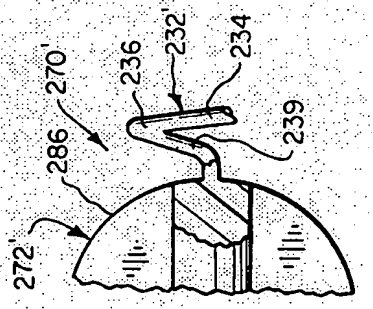
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FIG. 12

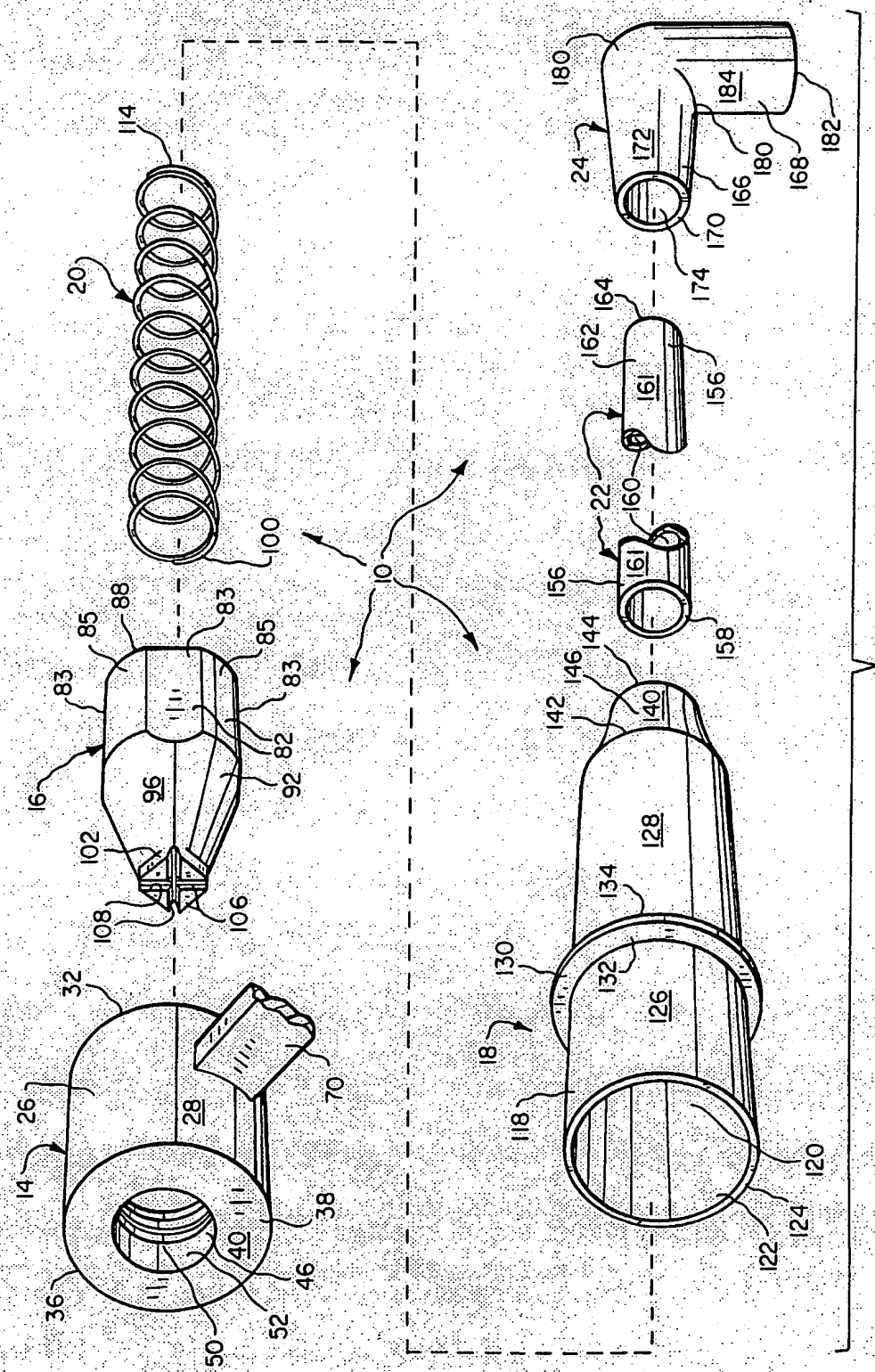
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FIG. 2

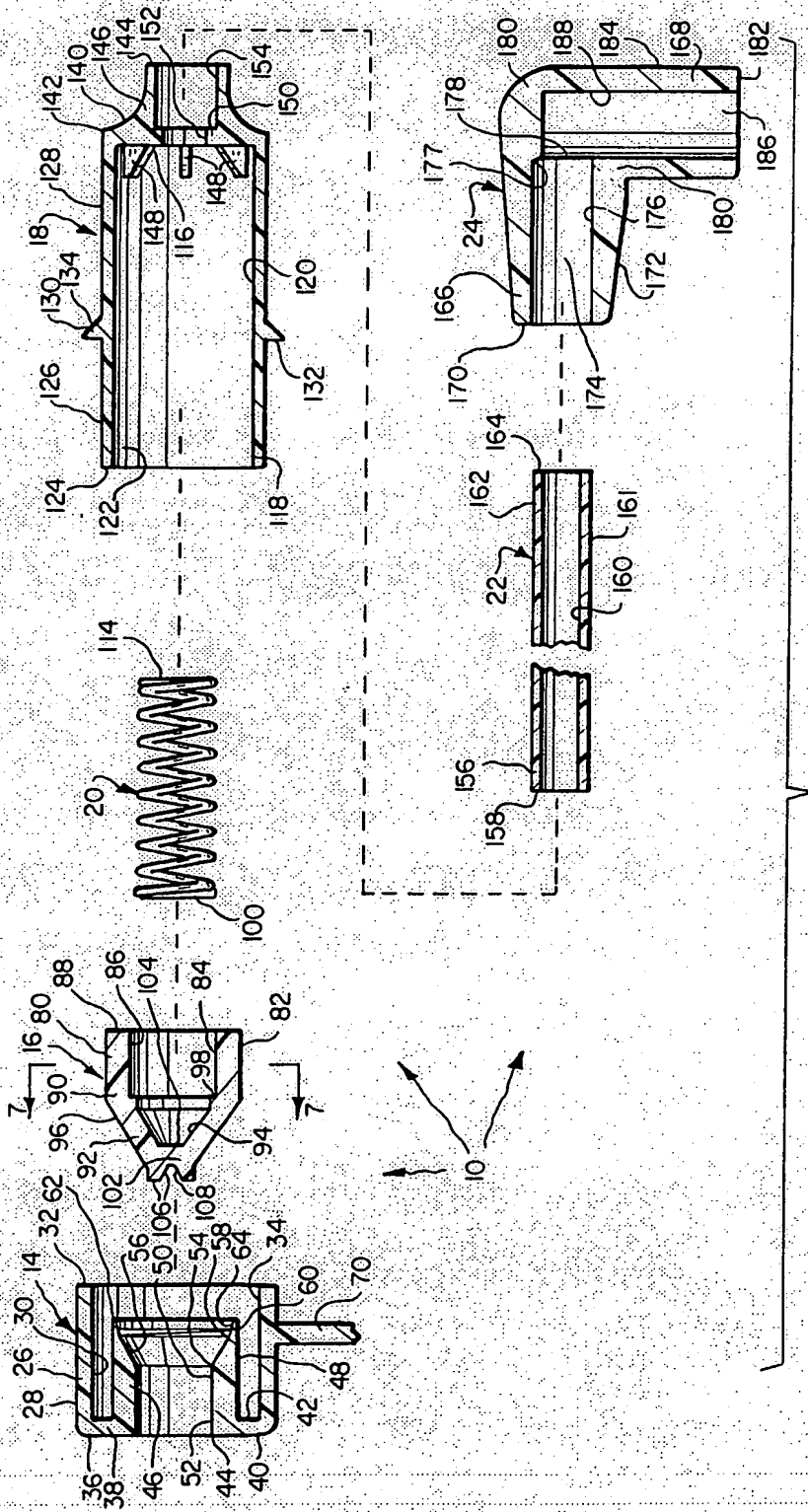

FIG. 3

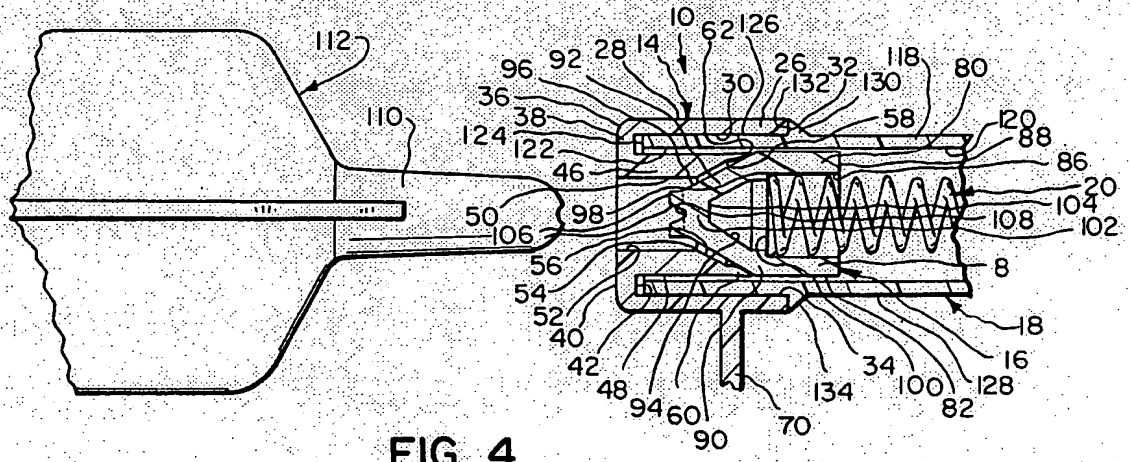

FIG. 4

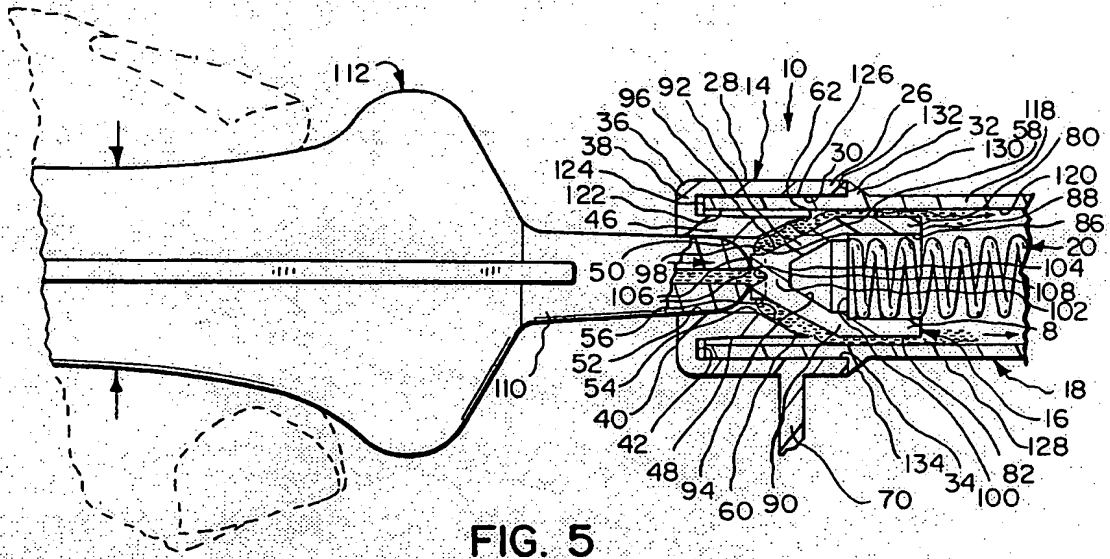

FIG. 5

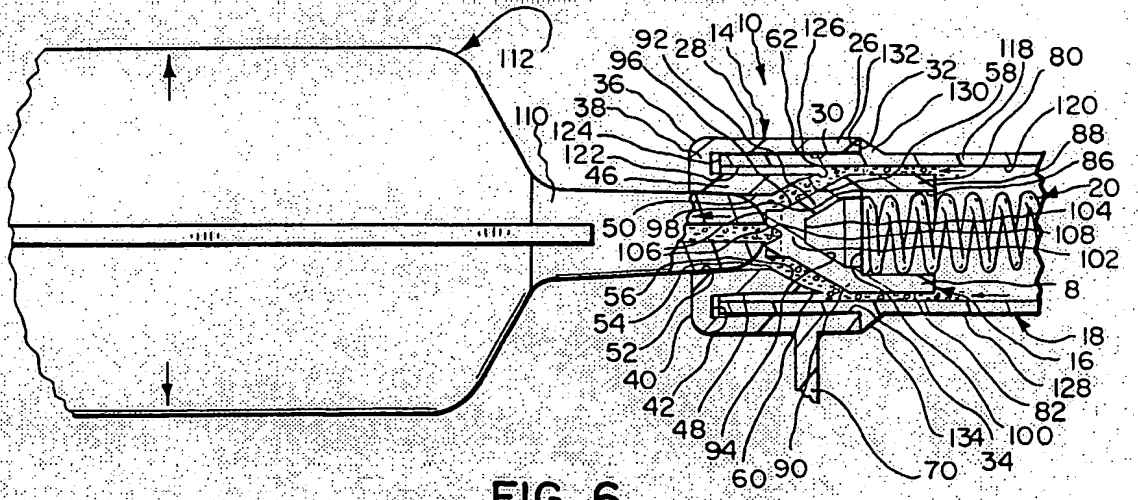

FIG. 6

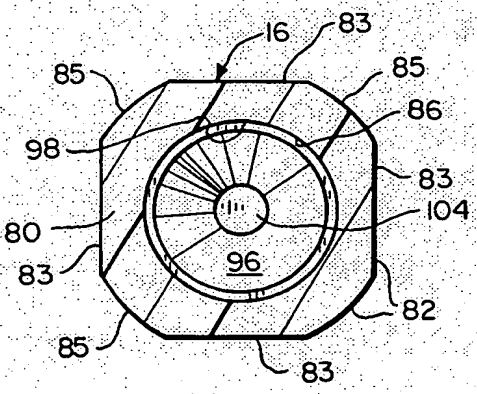

FIG. 7

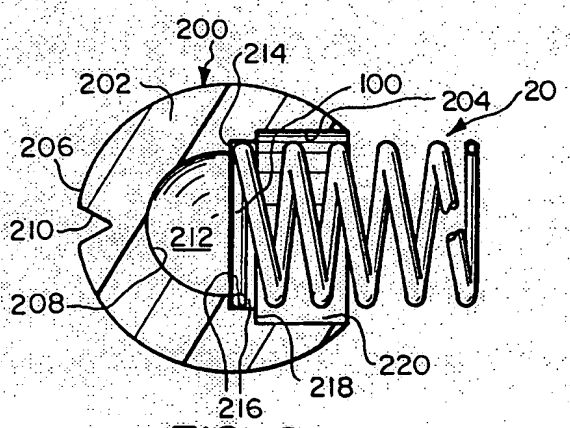

FIG. 8

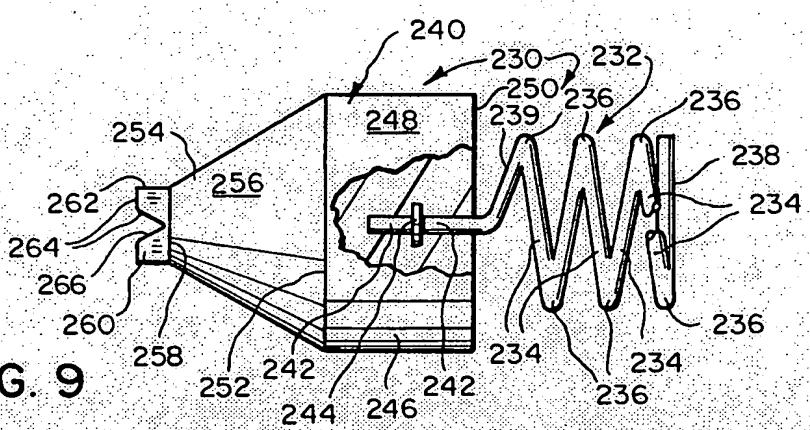

FIG. 9

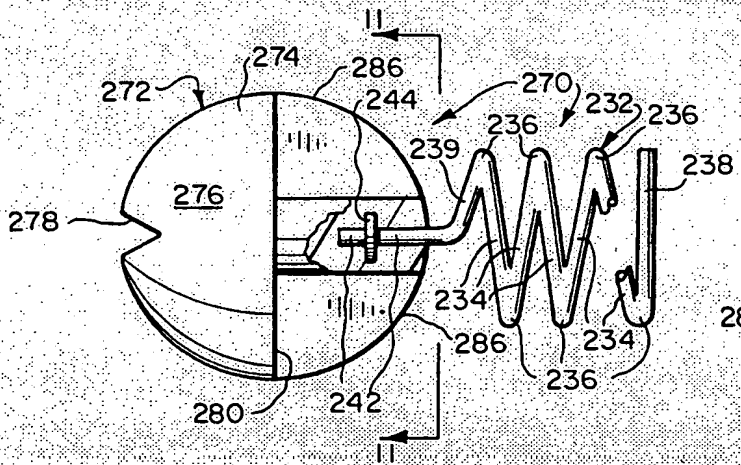

FIG. 10

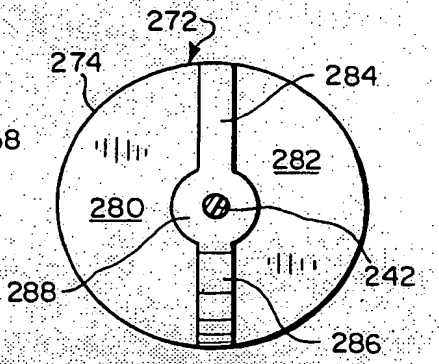

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/02570

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 16/00; A62B 9/06; F16K 51/00; F16L 29/00, 37/28
US CL :128/207.14, 203.12, 912; 251/149.7

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/207.14-207.16, 200.14, 200.23, 200.18, 203.12, 912; 251/149.7, 149.6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,429,856 (JACKSON), 07 February 1984, see entire document.	1-20, 25, 29, 31-34
Y	US, A, 1,534,913 (BUCK ET AL), 21 April 1925, see entire document.	1-20, 24, 25, 29, 31-34
Y	US, A, 3,731,717 (POTASH), 08 May 1973, see entire document.	6-9, 21-23, 26, 27, 32-34
Y	US, A, 3,486,730 (POTASH), 30 December 1969, see entire document.	18
Y	US, A, 3,035,617 (BREITENSTEIN), 22 May 1962, see figures.	10-12

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
20 JUNE 1995

Date of mailing of the international search report
30 JUN 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
KIMBERLY L. ASHER
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Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/02570

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,046,645 (HAGAN ET AL), 10 September 1991. See elements 40-47.	19 & 20
Y	GB, A, 13,630 (CARY), 16 July 1895. See figures.	30
A	CH, A, 68,559 (ALLIATA), 30 April 1914. See figures.	1-34
A	FR, A, 1,053,358 (OTOM), 02 February 1954. See figures.	1-34
A	US, A, 3,75,221 (MOCHIZUKI ET AL), 20 April 1971. See figures.	1-34
A	US, A, 2,327,611 (SCHEIWER), 24 August 1943. See figures.	1-34
X	US, A, 5,181,508 (POOLE, JR.), 26 January 1993, see entire document.	28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/02570

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/02570

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-23, 25, 26, and 28-34, drawn to a control mechanism and method.

Group II, claim(s) 24, drawn to a two-way valve.

Group III, claim(s) 27, drawn to a method of contemporaneous respiratory therapy.

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Not all claims require contemporaneous respiratory therapy.